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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventors: Thomas R. Cech et al.

Filing Date: January 18, 2002

Serial No: 10/053,758

Docket: 015389-002980US; 018/183

Title: ANTIBODY TO TELOMERASE REVERSE TRANSCRIPTASE

Art Unit: 1642

Examiner: Susan N.M.N. Ungar, Ph.D.

DECLARATION UNDER 37 CFR § 1.132
CALVIN B. HARLEY, Ph.D.

Commissioner for Patents
Alexandria VA 22313

Dear Sir:

I, CALVIN HARLEY, do hereby declare as follows:

I am the Chief Scientific Officer at Geron Corporation. I have been conducting research on telomere biology and biochemistry for over 15 years. I have 22 issued U.S. patents and over 35 academic publications on the subject.

My role at Geron is to oversee the company's entire scientific research program, including the development of human telomerase reverse transcriptase (hTRT) and telomerase inhibitors for human therapy.

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I am coinventor on the patent application indicated above. This is part of a series of U.S. patents and applications invented by scientists at the University of Colorado (Thomas Cech, Joachim Lingner, and Toru Nakamura) in collaboration with scientists at Geron Corporation (Karen Chapman, Gregg Morin, Bill Andrews, and myself). The application describes for the first time the isolation and characterization of the gene for hTRT. The application also describes how to express the gene to obtain purified hTRT protein, and how to use purified hTRT protein to obtain monoclonal and polyclonal antibodies specific for hTRT (paragraphs [0202] to [0210] of the published application).

I understand the Examiner has questioned whether hTRT specific antibodies could also be made using telomerase protein purified according to the Weinrich patent (U.S. Patent No. 6,517,834).

The Weinrich patent describes purification of the telomerase holoenzyme from human cells expressing hTRT, such as 293 cells. A six-step method shown in the example section involves preparing a nuclear extract, enriching for telomerase activity using ion exchange and other chromatographic techniques, and then using an oligonucleotide affinity agent that couples to the telomerase RNA component. The product obtained in this example was about 3,550 fold enriched compared with the starting extract.

The project to purify telomerase protein from human cells was lead by Dr. Scott Weinrich, and involved over twenty scientists and technicians. The method developed by Dr. Weinrich is still our preferred method for obtaining active telomerase protein complexed with telomerase RNA component. We and other companies have used telomerase purified according to the Weinrich method for extensive screening and testing of potential small molecule inhibitors of telomerase.

In spite of the importance of Dr. Weinrich's invention for use in drug screening, hTRT is still a minor component in the 3,550 fold enriched preparation, in terms of total protein content. The proportion of hTRT is too small in the preparation to generate a specific polyclonal antibody, or to screen hybridoma clones.

Now that the hTRT gene has been cloned and expressed, hTRT specific antibody has been made as described in this application.

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I hereby declare that all statements made in this Declaration of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

2004.09.20
Date

Calvin B. Harley, Ph.D.
Menlo Park, CA